



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Michael John Reed et al.
Serial No. : 10/084,235
For : STEROID SULPHATASE INHIBITORS
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DECLARATION OF PROFESSOR BARRY V.L. POTTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

PROFESSOR BARRY V. L. POTTER DECLARES AND STATES THAT:

1. I am one of the named inventors on the above-captioned application ("the present application"). I am familiar with its text and prosecution, including the November 14, 2003 Office Action. Moreover, I am an author and inventor on articles and patents in the field to which the present invention pertains, such that I am considered an expert in the field to which the present application pertains. I am the Professor Barry V.L. Potter who made a November 23, 2002 Declaration in U.S. application Serial No. 09/794,853, filed February 27, 2001, a copy of which is attached hereto, and which is incorporated herein by reference. Further, I am fluent in

both the spoken and written forms of German. Accordingly, I respectfully submit that I am qualified to speak and render opinions about the present application and its prosecution. And as this Declaration is in response to the November 14, 2003 Office Action, I respectfully request reconsideration and withdrawal of objections to and/or rejections of the application, in view of matters discussed herein.

2. In particular, I am advised and therefore Claims 6-11, 17, 18 and 20 are rejected under 35 U.S.C. 103(a) allegedly as being unpatentable over The Registry Handbook (1984 Supplement) in view of Schwarz et al. (DD 114806) and Hirsch (US Patent No. 4,075,351), which I have read and with which I am familiar; and, this Declaration is directly responsive to that rejection, reconsideration and withdrawal of which I respectfully request.

3. The Registry Handbook merely provides the compound name, "19-norpregna-1,3,5(10)-triene-20-yne-3,17-diol, 3-sulfamate".

4. From the mere naming of a compound, such as in The Registry Handbook, or a mere drawing of a compound, as in incorrect Abstract of DD 207447 (cited in USSN 09/794,853 by the same Examiner as in the present application), the skilled artisan is NOT provided with an enabling disclosure of how to make and use the compound.

5. Prior to the effective filing date of the present application (August 29, 1991), there was no teaching or suggestion in the art, of which I am aware, of reacting a steroid, such as oestrone, 17 Beta-oestradiol, 17alpha-ethinyl-17Beta-oestradiol, 17alpha-oestradiol or oestriol, with unsubstituted sulfamoylchloride, or a polycyclic alcohol having at least four rings with at least two of those rings being fused with unsubstituted sulfamoylchloride.

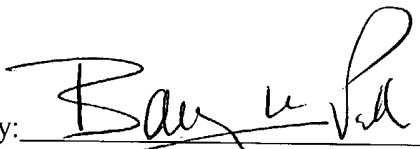
6. Schwarz employed a sterol and a substituted sulfamoylchloride. In my expert opinion, based upon my education, training, and experience, including personal experience working with Prof. Schwarz, the teachings in Schwarz cannot be applied to arrive at the compound of The Registry Handbook; and, more generally, cannot be applied to synthesize unsubstituted steroid sulphamates or unsubstituted polycyclic sulphamates having at least four rings with at least two of those rings being fused. There is no teaching or suggestion in Schwarz of synthesizing unsubstituted steroid sulphamates or unsubstituted polycyclic sulphamates having at least four rings with at least two of those rings being fused by reacting a steroid, such as oestrone, 17 Beta-oestradiol, 17alpha-ethinyl-17Beta-oestradiol, 17alpha-oestradiol or oestriol, with unsubstituted sulfamoylchloride, or a reacting a polycyclic alcohol having at least

gestrone, 17 Beta-oestradiol, 17alpha-ethinyl-17Beta-oestradiol, 17alpha-oestradiol or oestriol, with unsubstituted sulfamoylchloride, or a reacting a polycyclic alcohol having at least four rings with at least two of those rings being fused with unsubstituted sulfamoylchloride. And, if one attempted to apply reaction conditions of Hirsch, in my view, failure would also be met; for instance, in my view, a steroid would not be soluble in the solvent systems of Hirsch. Accordingly, Hirsch, either individually or in combination with Schwarz, cannot supply the deficiencies of the mere compound name in The Registry Handbook.

8. Therefore, The Registry Handbook (1984 Supplement) in view of Schwarz et al. (DD 114806) and Hirsch (US Patent No. 4,075,351) fails to teach or suggest 19-norpregna-1,3,5(10)-triene-20-yne-3,17-diol, 3-sulfamate as asserted in the Office Action.

9. I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 13.05.2004

By: 

PROF. BARRY V. L. POTTER

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